CRS Programme Evaluations

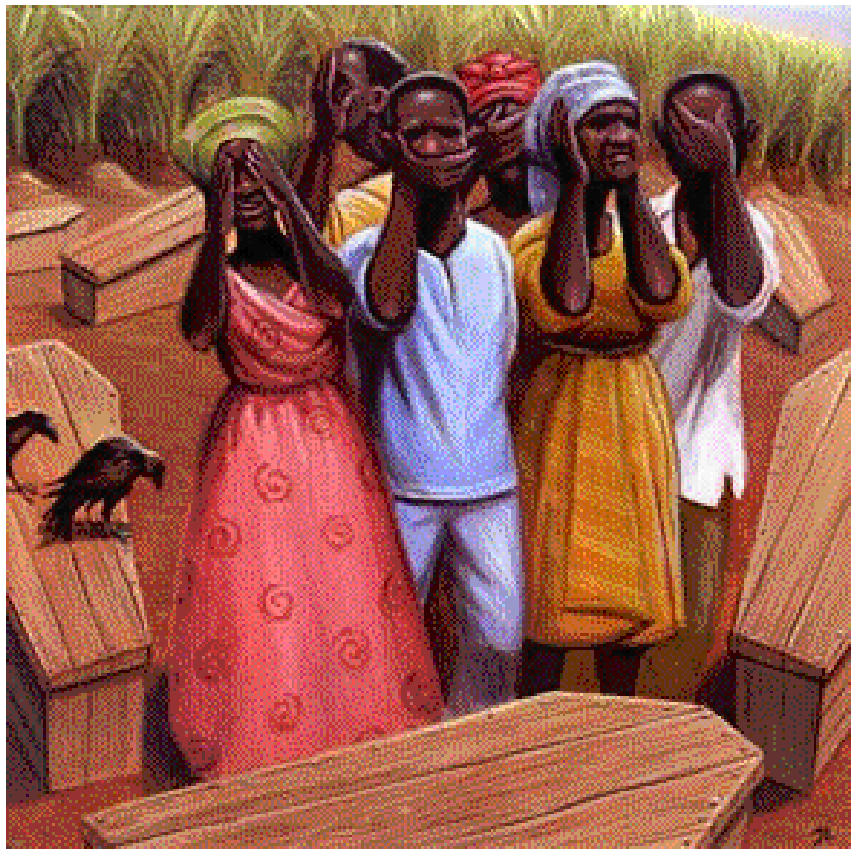
Des Martin & Robin Wood

Kimera Solutions

UNAIDS estimates for sub-Saharan Africa for 2004

2.3 million (2.1 – 2.6) deaths from AIDS

>6,000 deaths per day



ART Evaluation Parameters

- **Individual**
  - adherence
  - CD4 & viral load
- **Programme**
  - pre & on treatment mortality
  - patient retention
  - morbidity and health care usage
  - viral suppression rates
- **Population**
  - programme coverage
  - improved population health

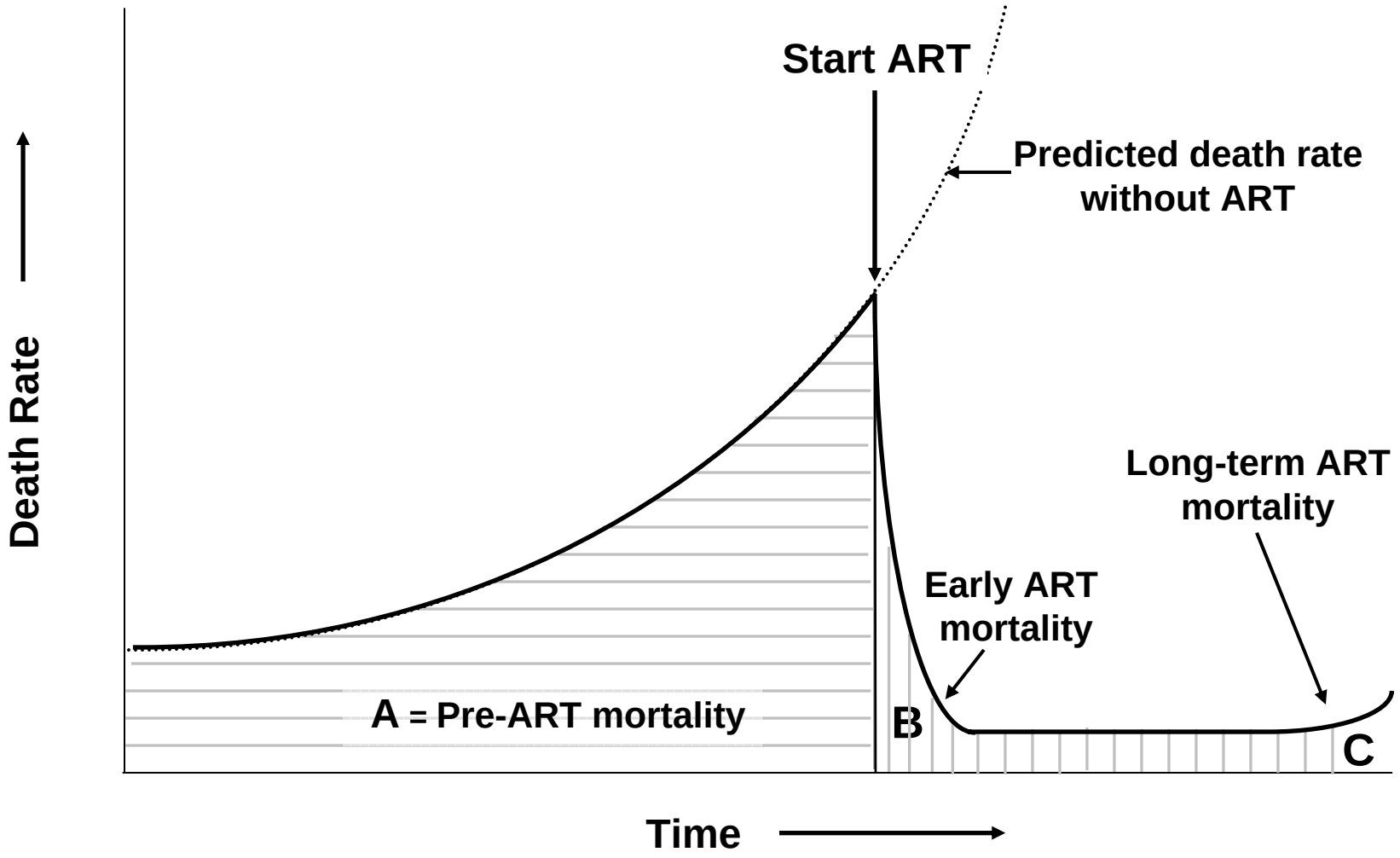
Programme Parameters

- Population
  - Monitor patient outcomes from first entry to programme
  - Population coverage: sources of patients
  - Extended coverage will reduce entry CD4 and clinical stage
- Early programme outcomes
  - Measure pretreatment morbidity & mortality
- On treatment outcomes
  - Monitor loss to follow up
  - Monitor adherence via drug collections
  - Toxicities, drug switches
  - Laboratory, viral load, CD4

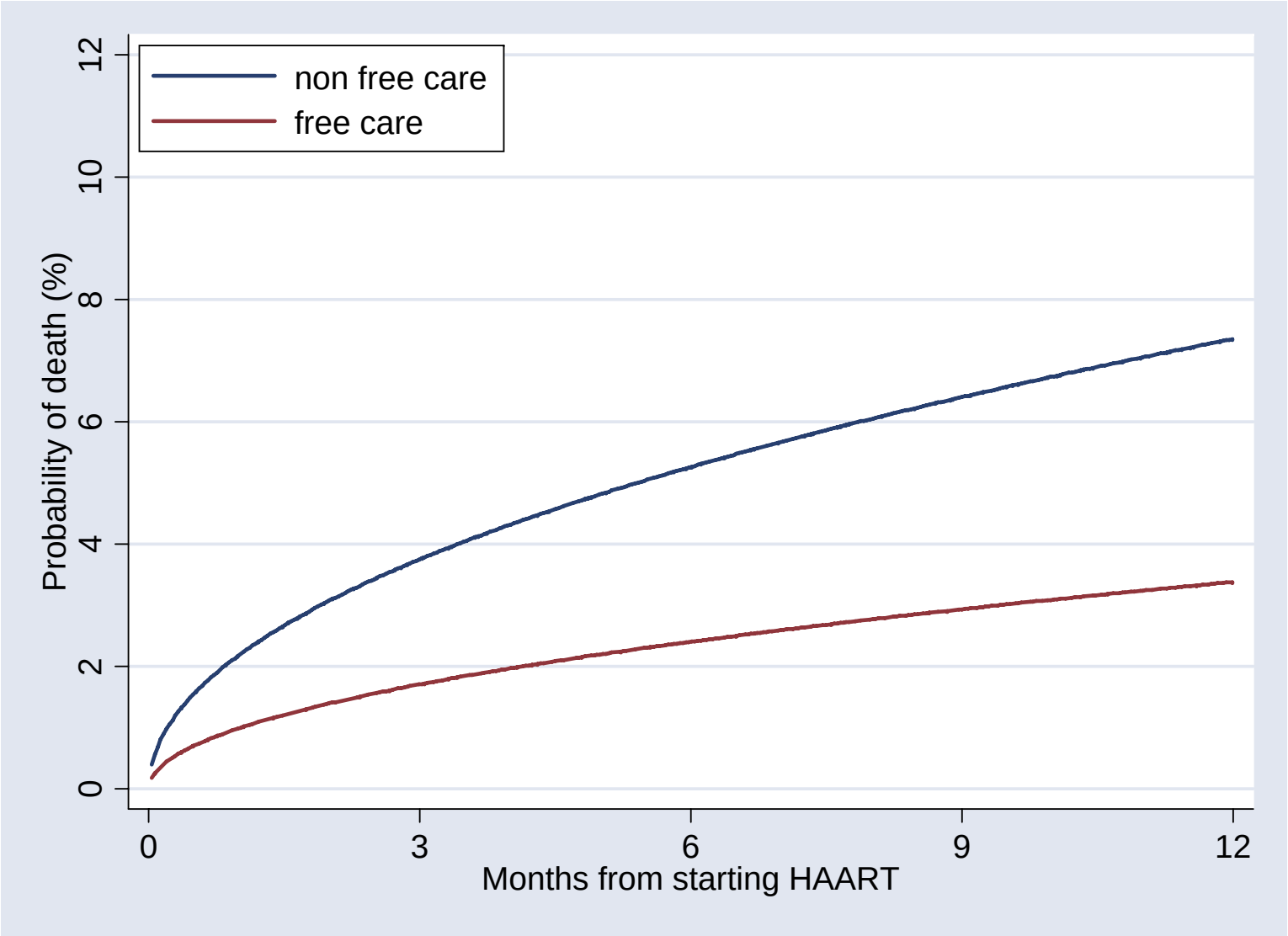
Estimated number of people requiring ARV therapy & percentage coverage, December 2004

Some parameters giving rise to variability between programmes

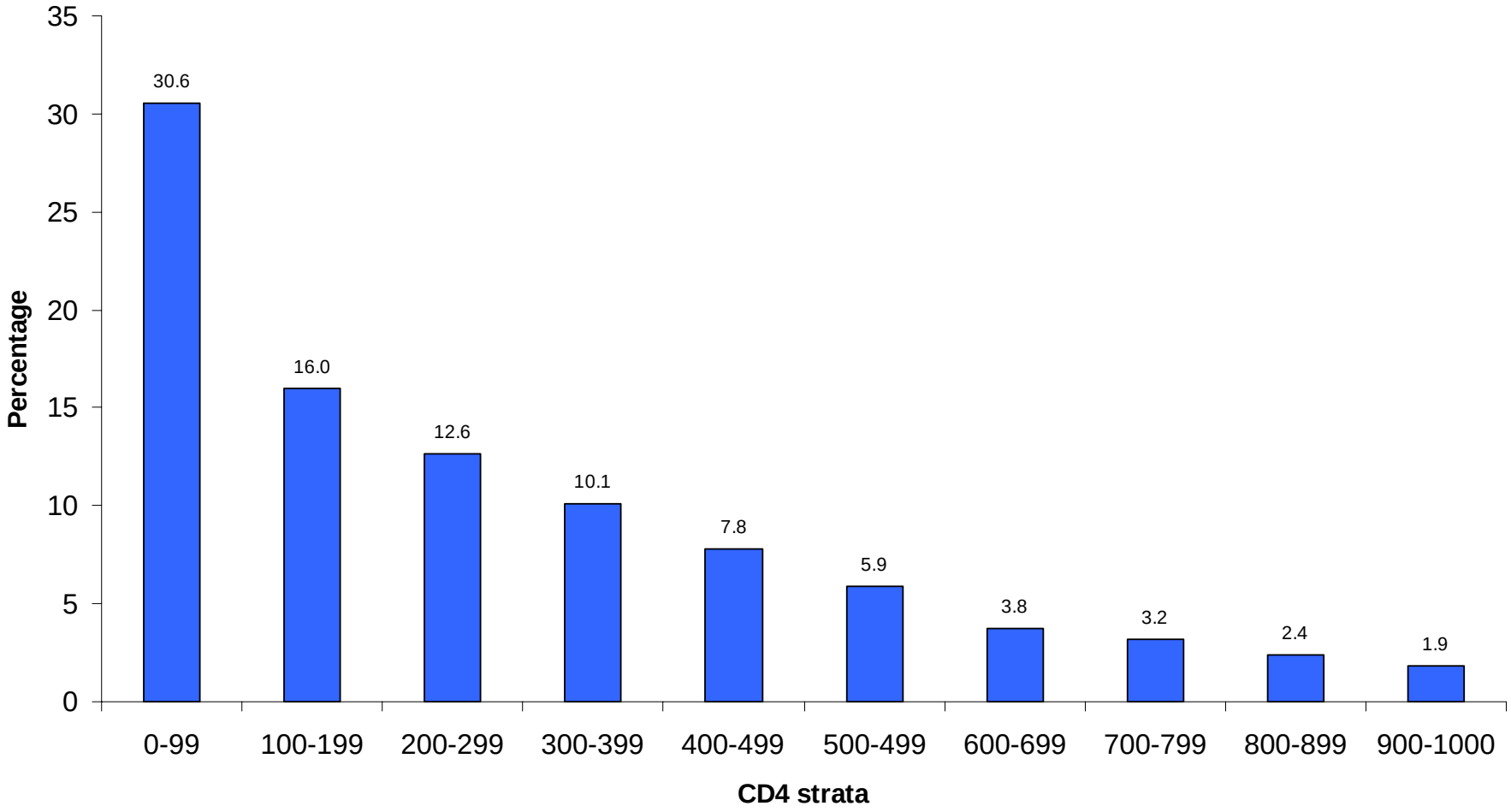
Time Periods for Risk of Death in Patients Accessing ART



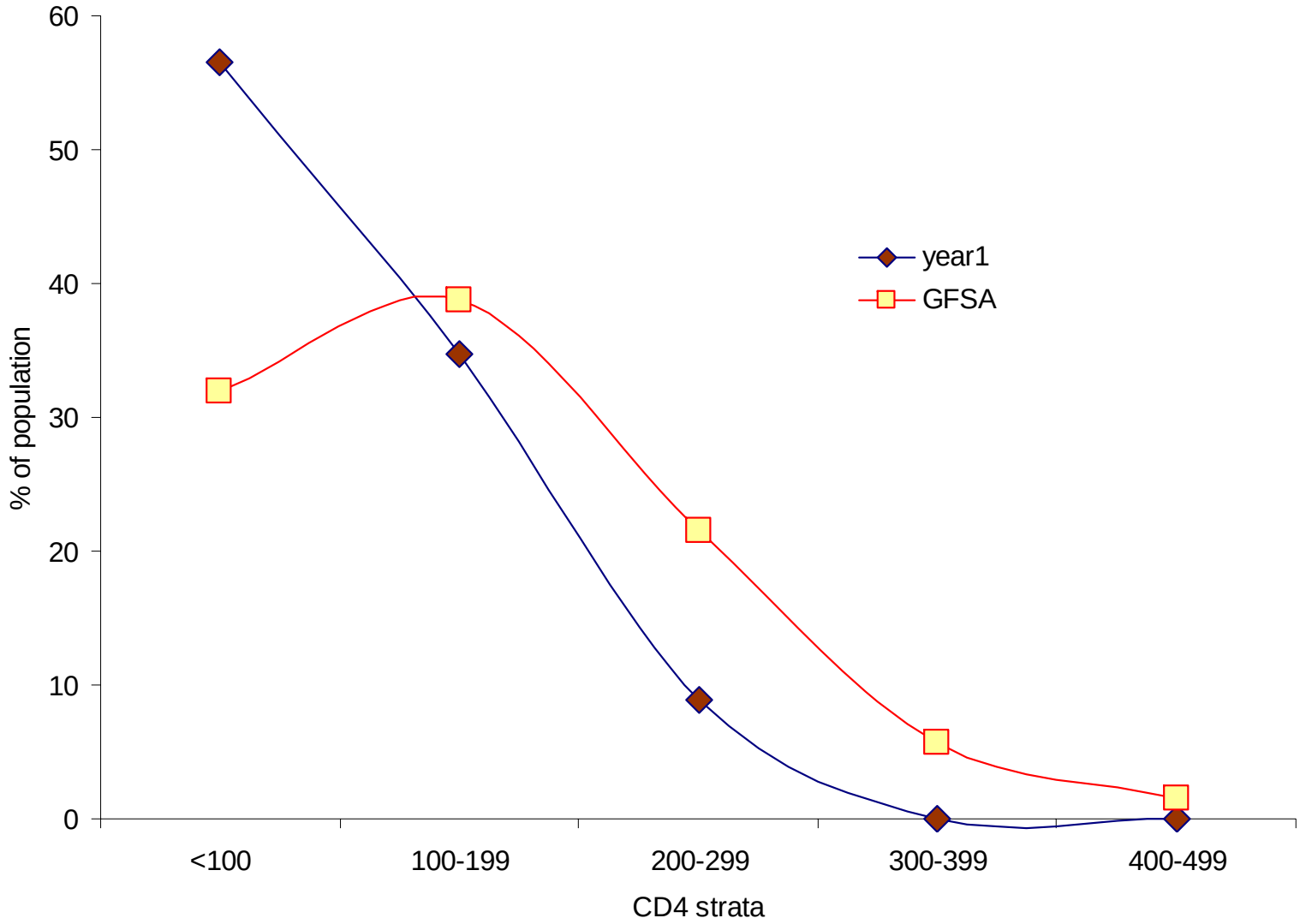
Hazard ratio for death in relation to free care



Distribution of CD4 counts in Public Sector Hospitals 2000-2003 *(n=15495)*

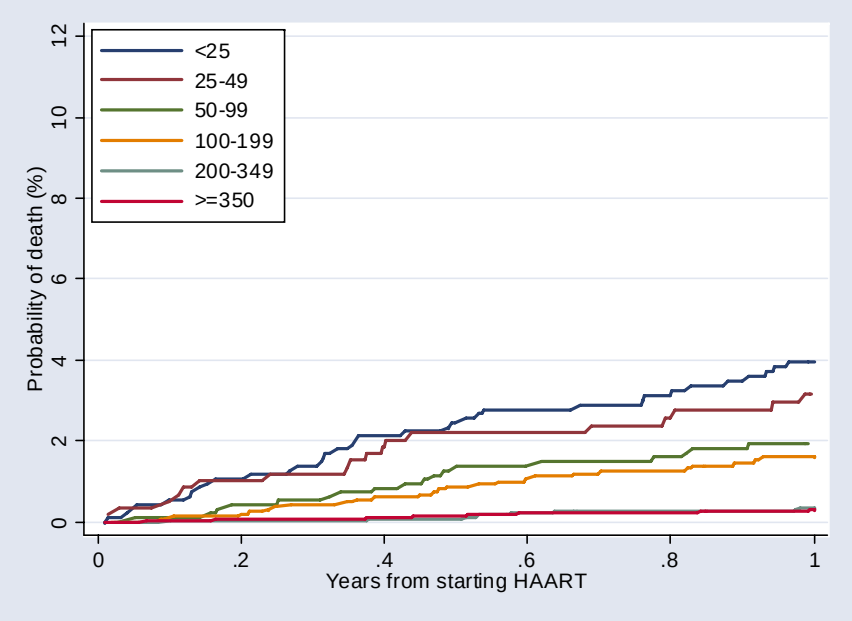


CD4 strata: Gugulethu & workplace ART programs

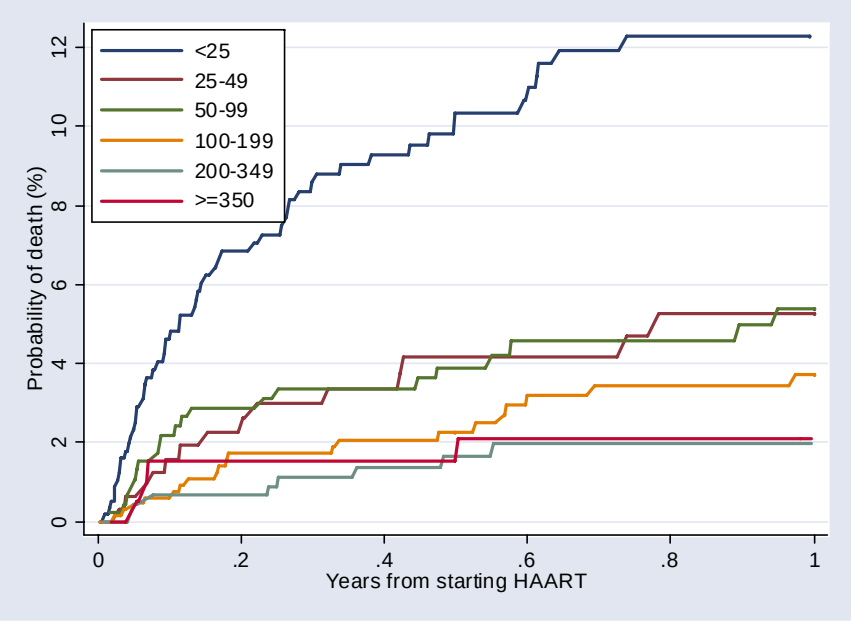


Prognosis of Drug Naïve Individuals starting HAART Stratified by CD4 Cell Count

ART CC (NORTH, excluding IDU)
N=10,174



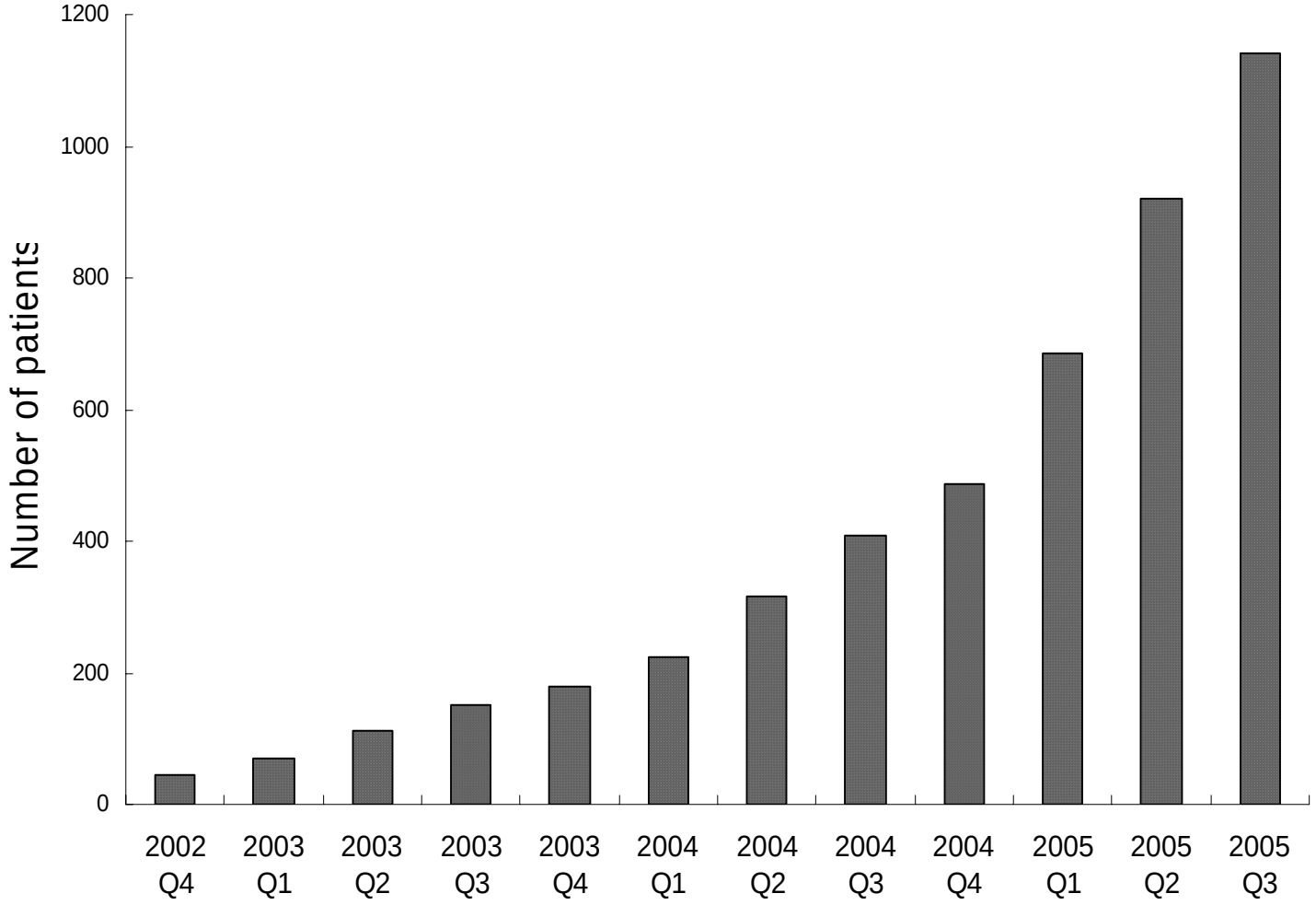
ART LINC (SOUTH)
N=3,044



North countries: Canada, EuroSIDA, France, Germany, Italy, Netherlands, Switzerland, UK, USA
South countries: Botswana, Brazil, Cameroon, Cote d'Ivoire, India, Malawi, Morocco, Nigeria, Senegal, South Africa, Thailand, Uganda

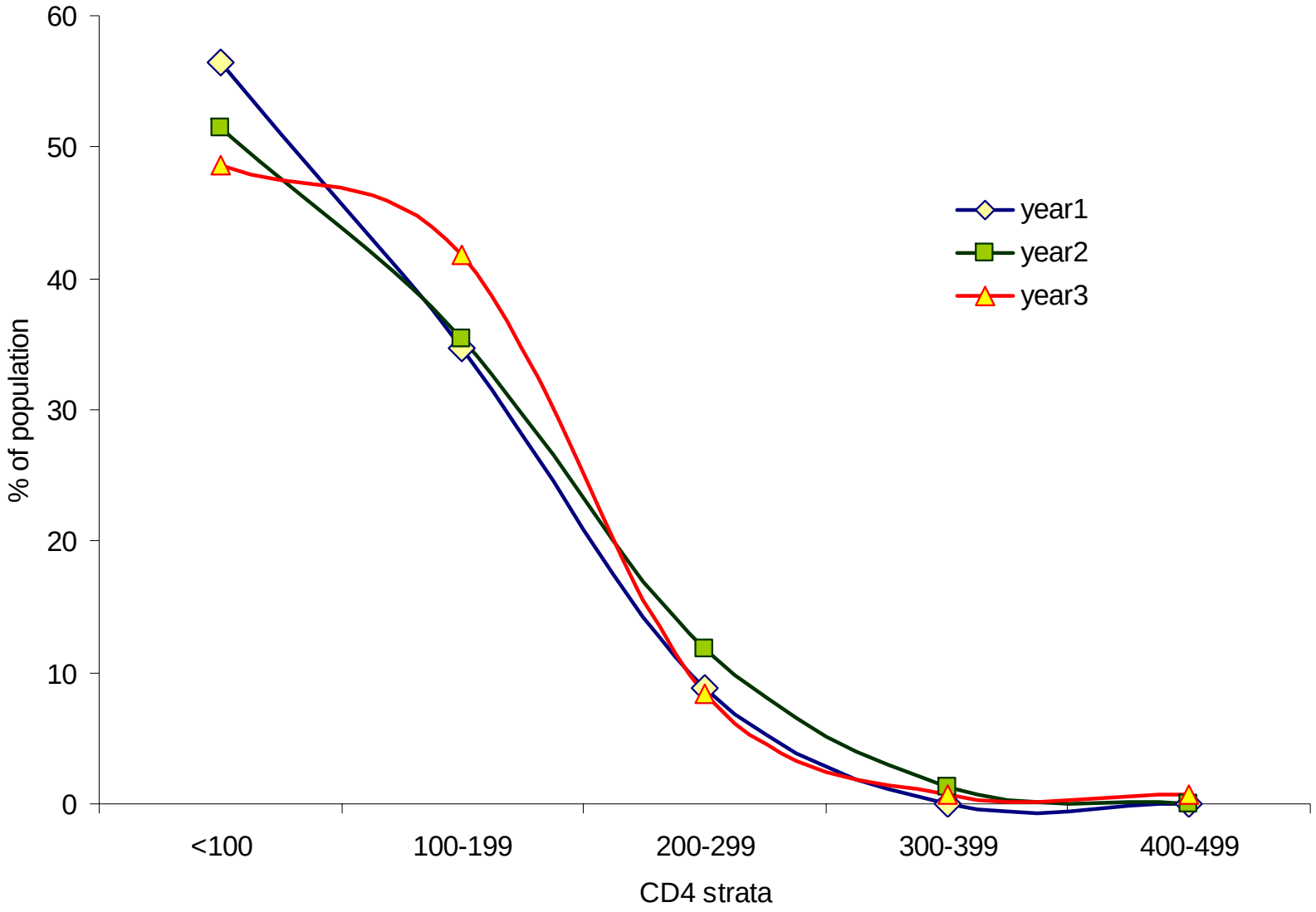
ART-LINC & ART-CC collaborations

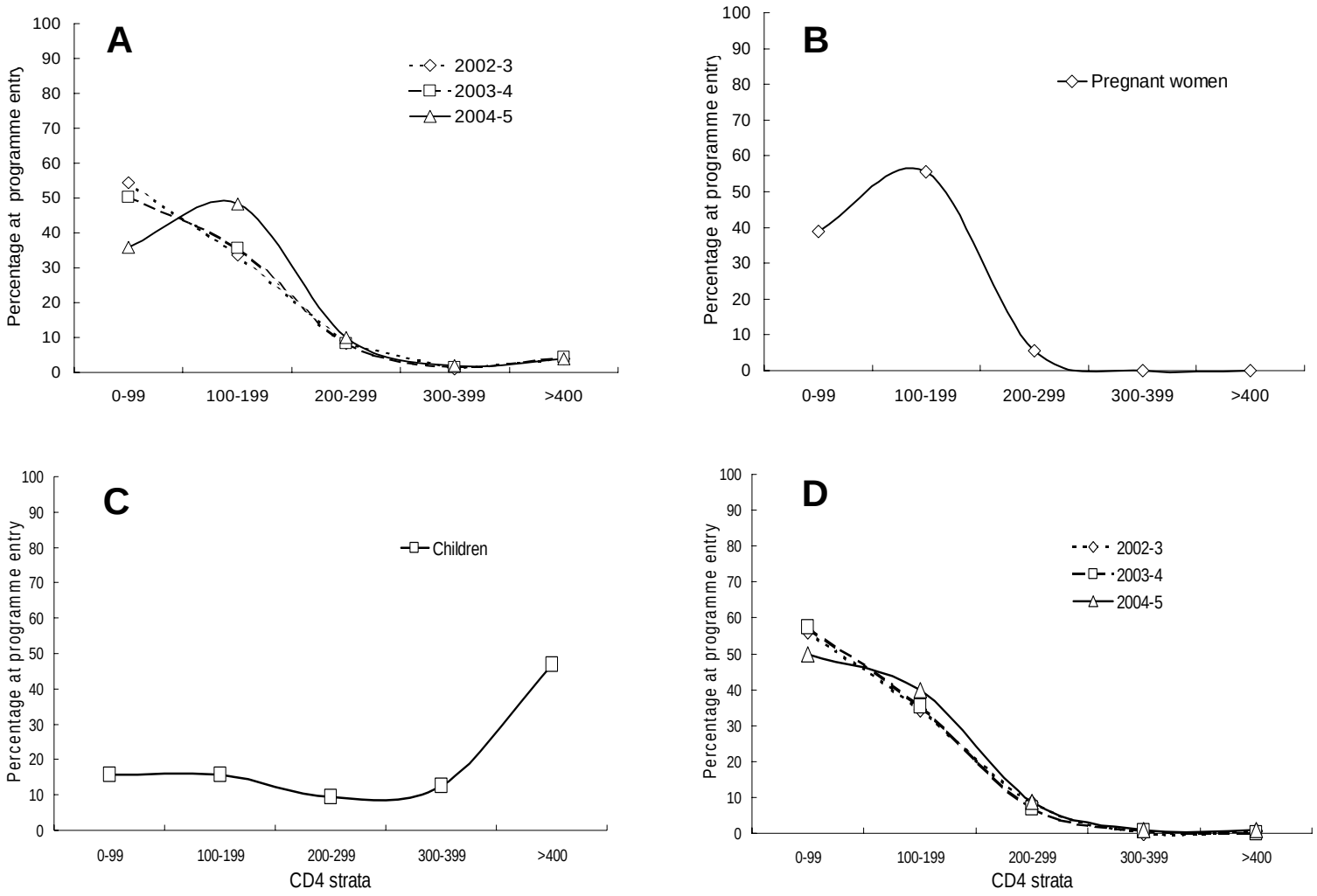
Recruitment and Staffing 2002-5



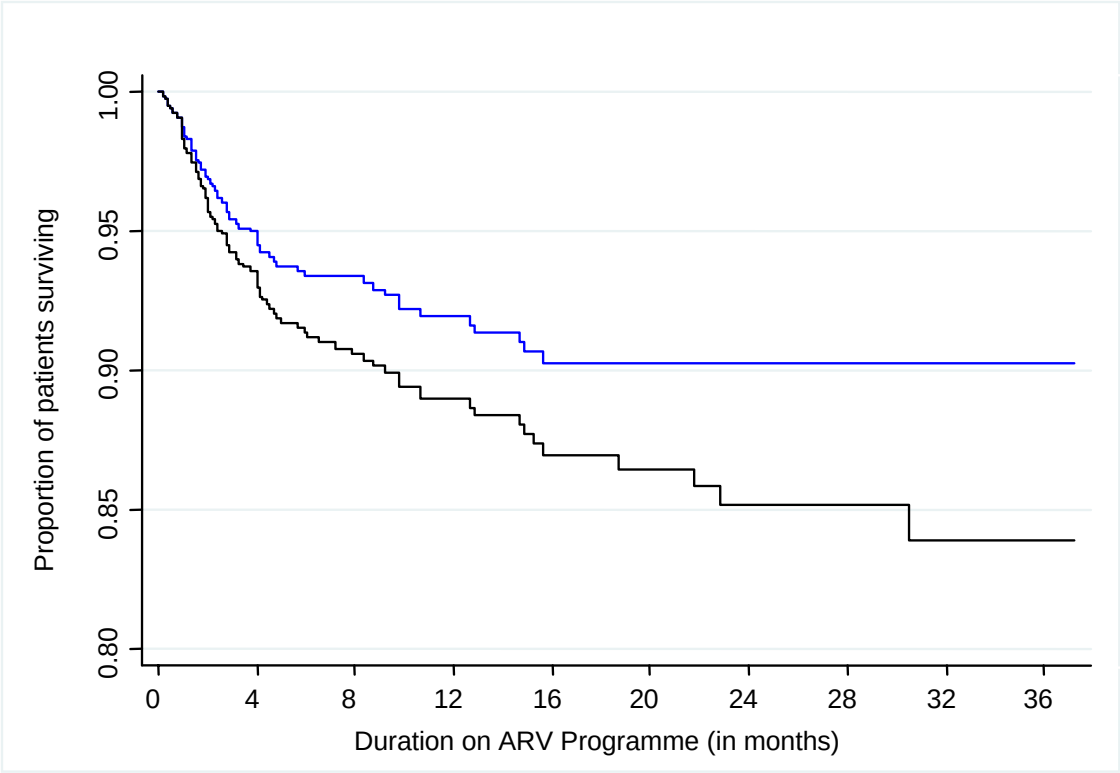
Doctors	1	1	1	1	1	1	2	2	2	4	4	4
Nurses	1	1	1	1	1	1	2	3	3	3	3	3
Counsellors	6	6	8	8	13	14	14	18	18	24	24	28

CD4 strata in 3 years of Gugs program




A
2002-3
2003-4
2004-5
Percentage at programme entry
0-99
100-199
200-299
300-399
>400
B
Pregnant women
C
Children
CD4 strata
D

Programme Deaths & Loss to Follow Up



Censored for: End of Follow-up;
Transfers Out;
Loss to Follow-up (mortality curve only)

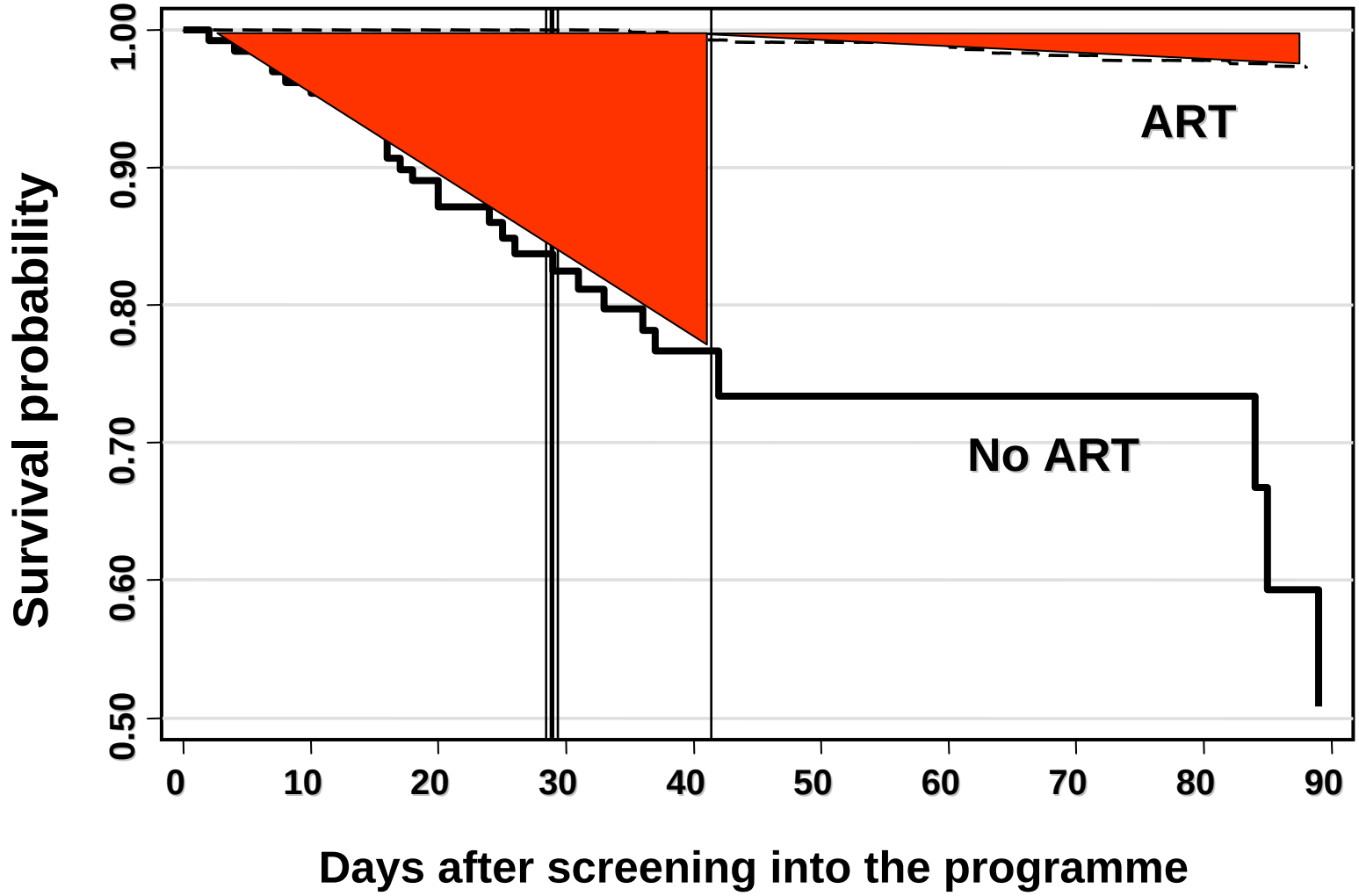
Excludes: Children & Transfers In.

Death of patient

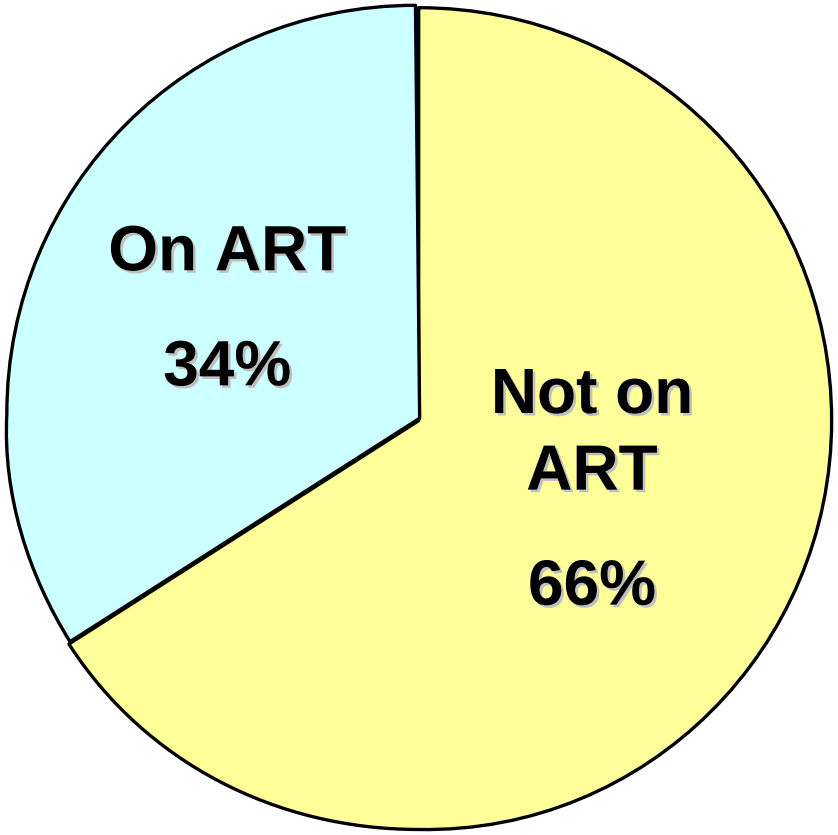
Death or Loss to Follow-up of patient

0	4	8	12	16	20	24	28	32	Duration on ARV Programme
927	641	421	328	229	162	127	86	51	Number at risk at end of period
	41	10	6	5	0	0	0	0	Deaths
	12	8	1	1	1	2	0	1	Losses to follow-up

Survival From Enrolment into ART Programme

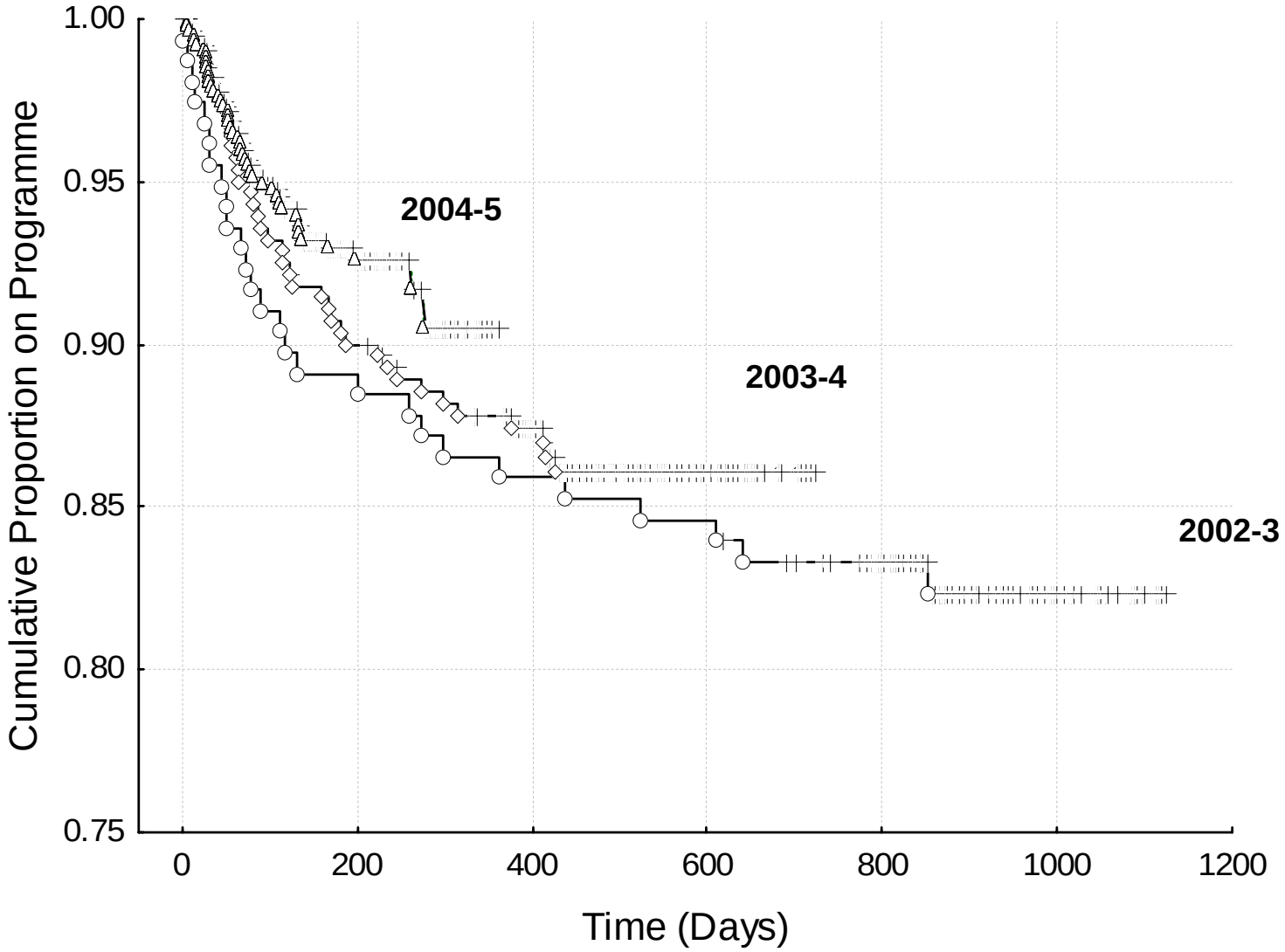


In-programme deaths in the first 3 months from enrolment

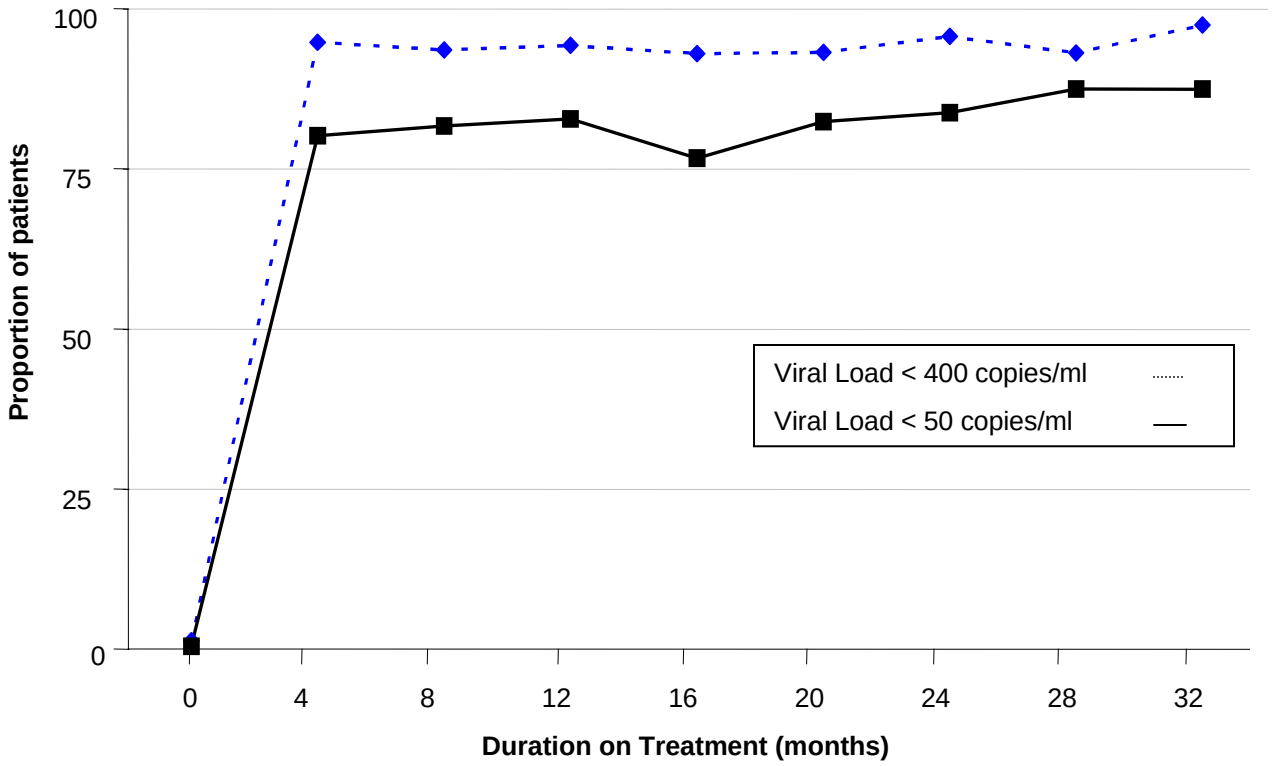


On-treatment analysis misses 66% of in-programme deaths during the first 3 months

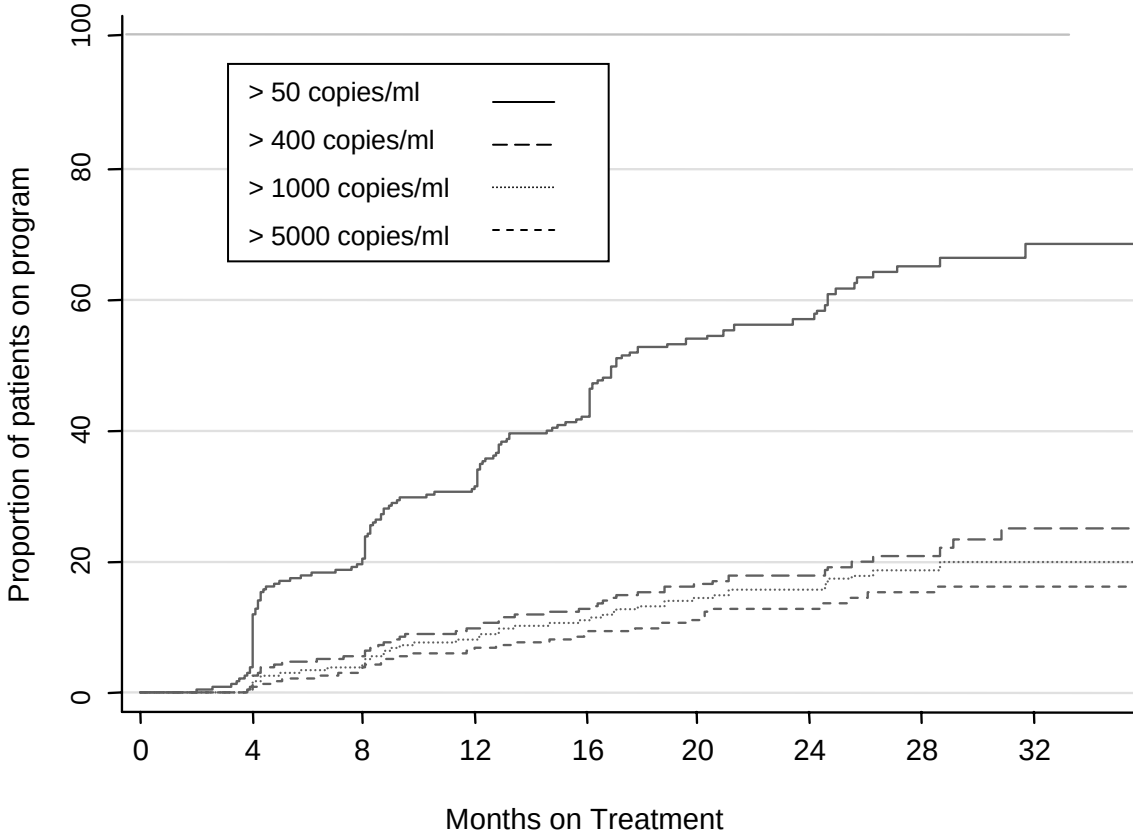
Programme Survival Year by Year Analysis



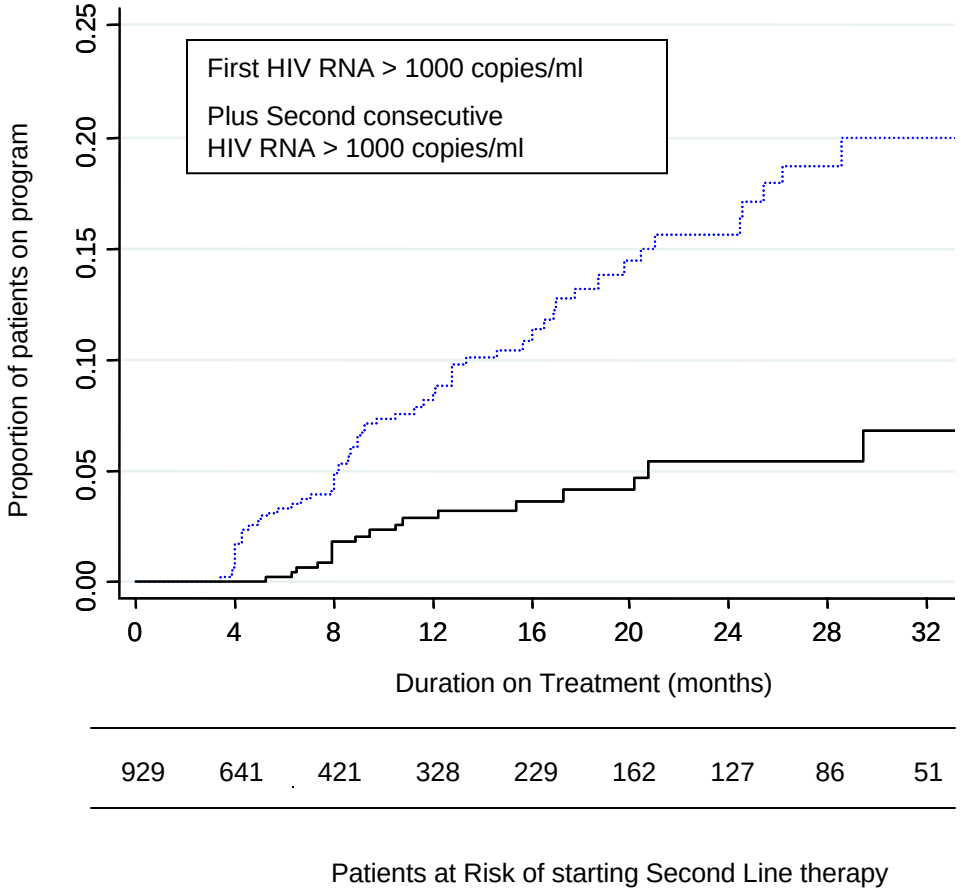
Utility of Viral Load Monitoring



First HIV RNA test result above various thresholds



Kaplan-Meier estimate for time to event



CRS Preliminary Evaluation

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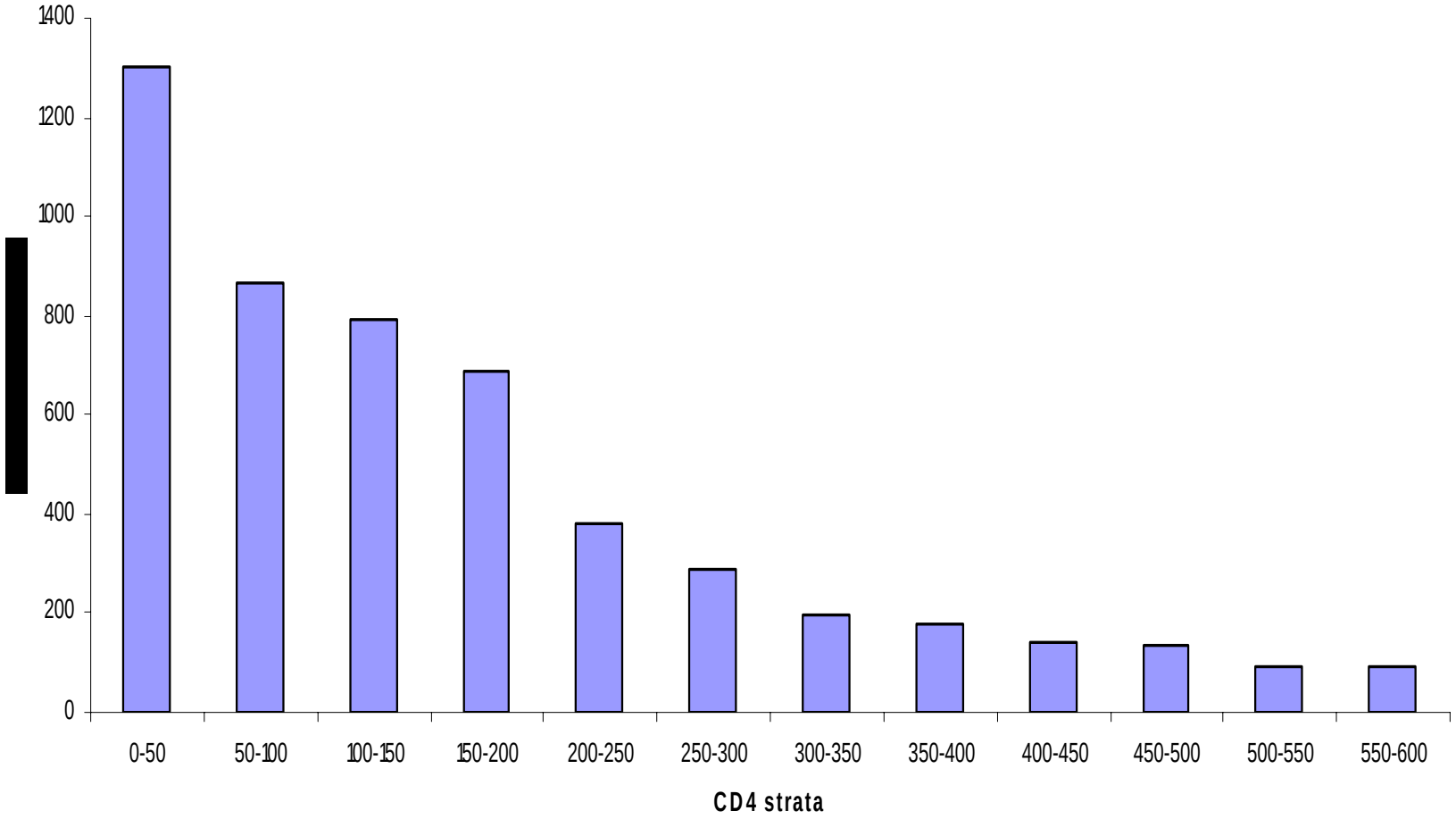
Sites with patient input data analysed

Site name	No	Patients
St Mary's	Site 1	1238
Sinosizo	Site 2	240
Eshowe	Site 3	111
Sizanani	Site 4	465
Nazareth	Site 5	214
Rustenburg	Site 6	449
Holy Cross	Site 7	90
Winterveldt	Site 9	218
Bethulie	Site 10	91
Bethal		345

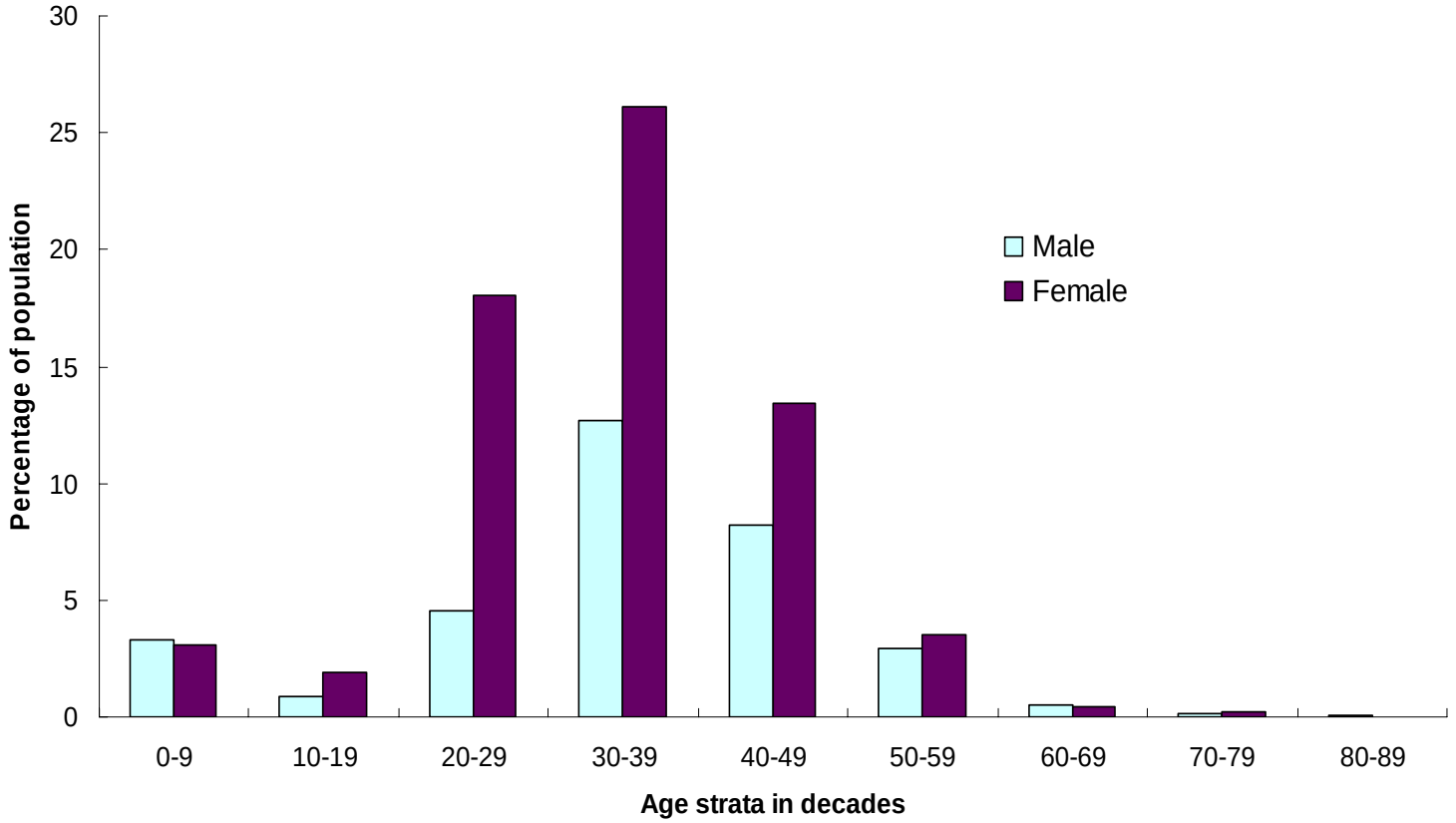
Site name	No	Patients
Bela Bela	Site 12	193
Orange Farm	Site 17	124
Middelburg	Site 18	52
Cradock	Site 19	325
Tembalethu	Site 21	228
Centocow		326
Groot Kei		99
Sophumelela		502
Masibambisane		167
Total		6529

CD4 Values at Baseline Screening (n=5516)

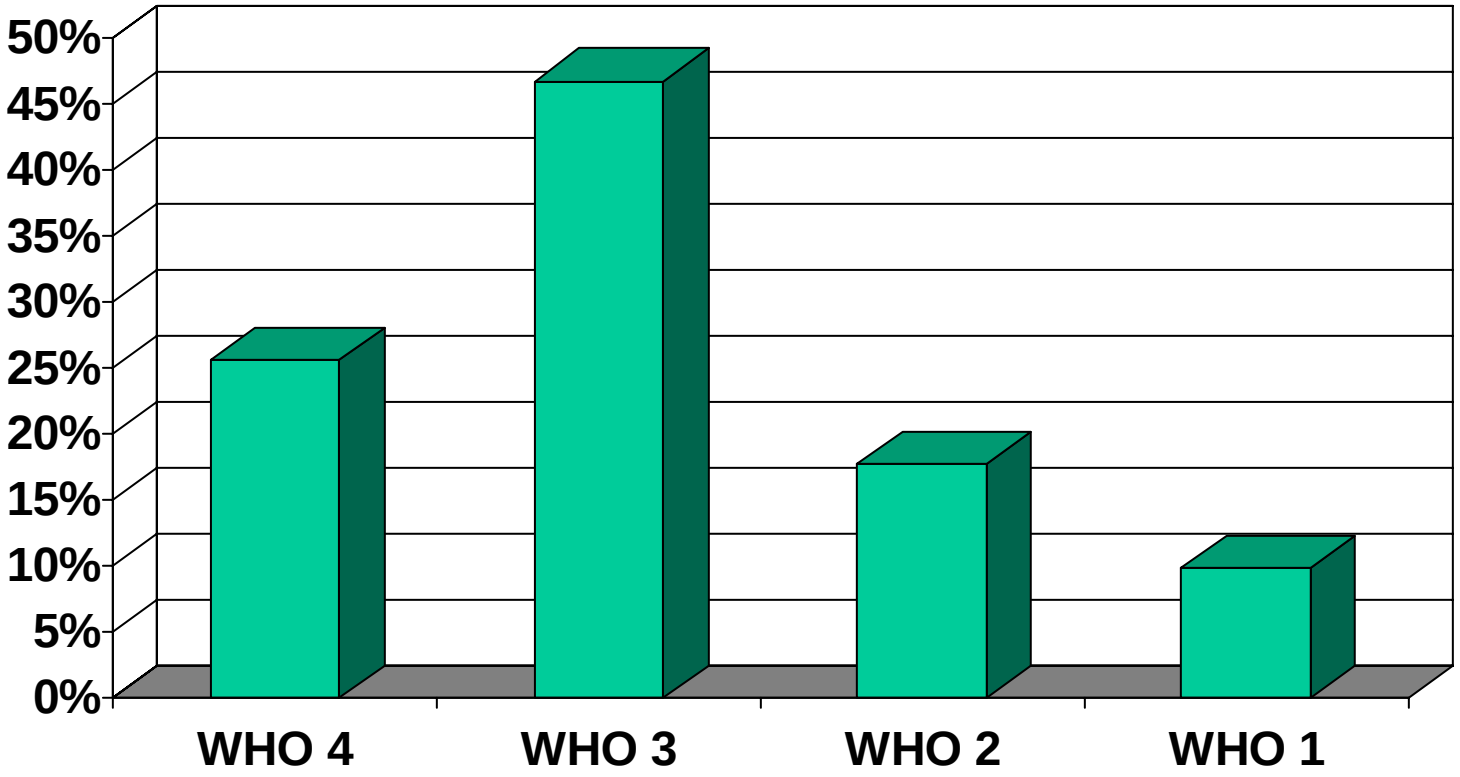


Distribution of Cohort by Age and Gender

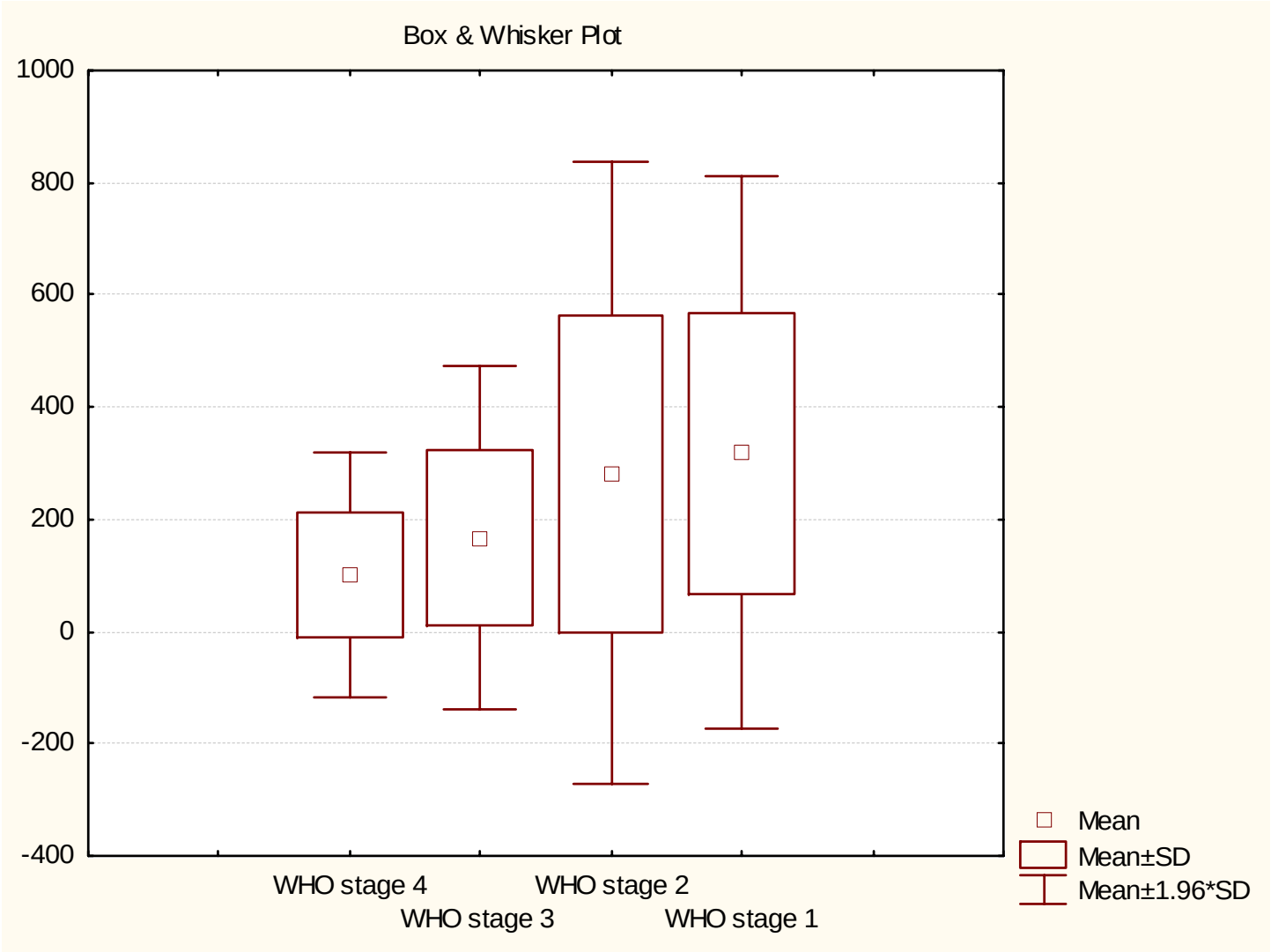
Median age = 34 yrs, range 1mth-85yrs



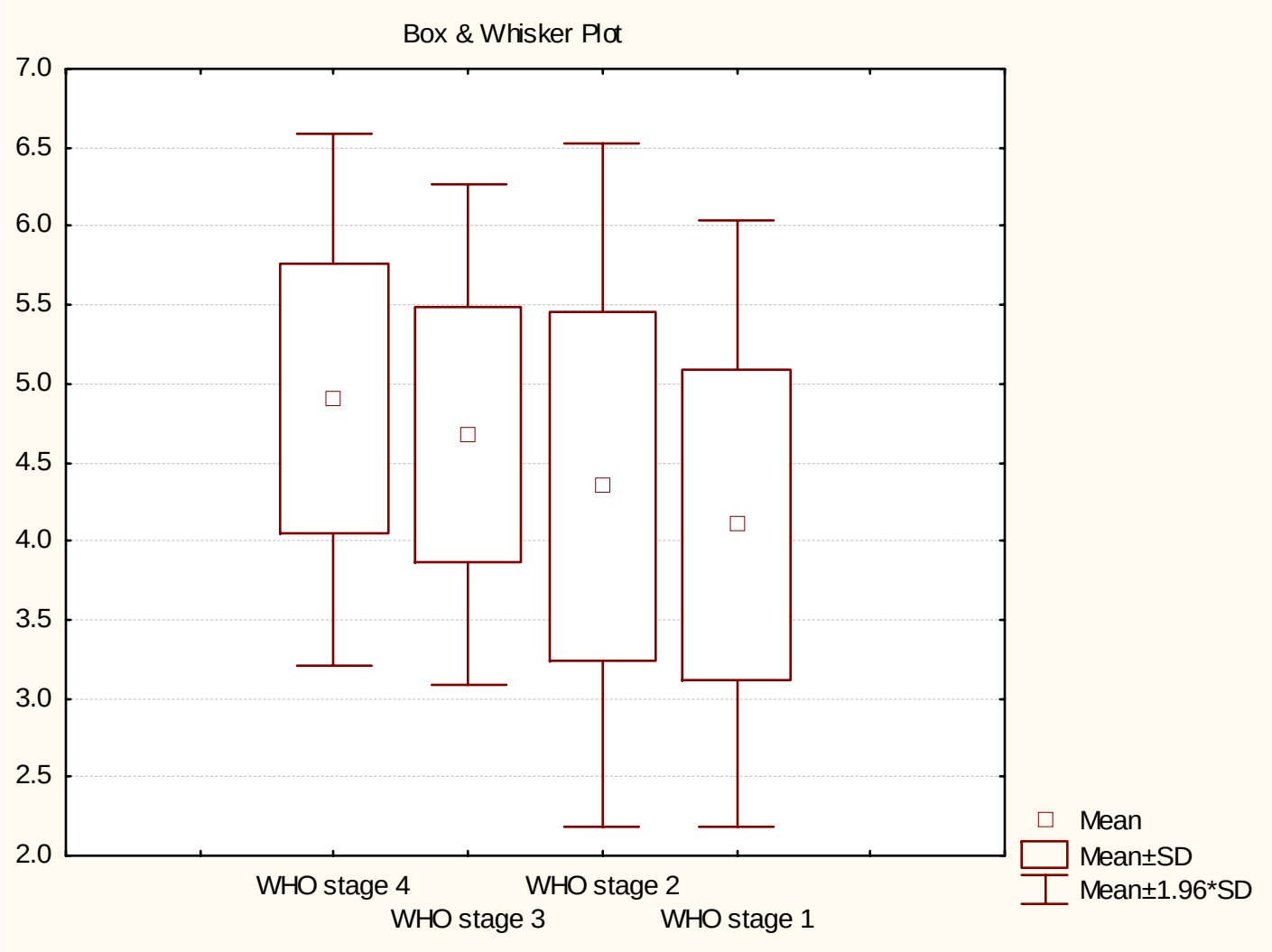
World Health Organization Clinical Stage at Baseline (n=2390)



Box and Whisker Plot of WHO Stage and CD4 Count



Box and Whisker Plot of WHO Stage and Viral Load



Children <10 years

- N=490, 54% female
- Median base line CD4 337, Viral load 67,889, 4.83 $\log_{10}$
- 6 weeks VL= 53, 1.2 $\log_{10}$
- 12 weeks VL = 49, 1.69 $\log_{10}$
- 6 months VL =50, 1.71 $\log_{10}$
- Deaths = 28
  - 10 before Rx, time = 13 days from screen
  - 18 on Rx, time = 17 days on treatment

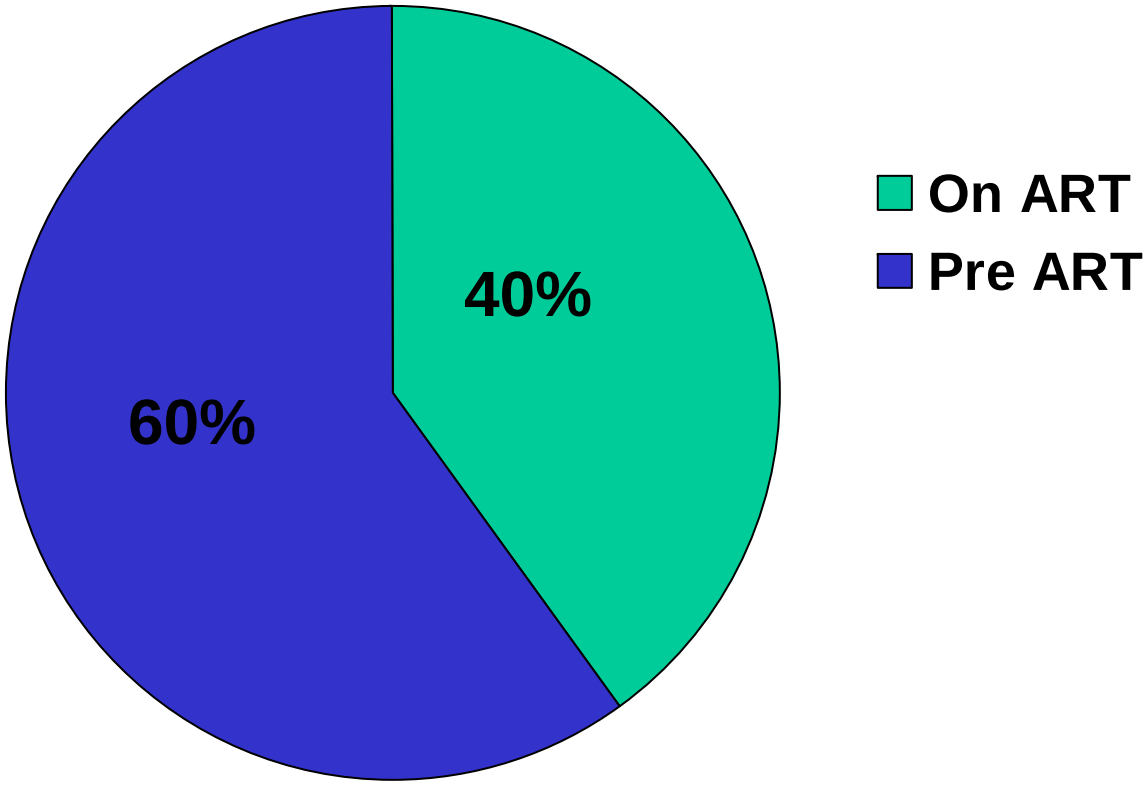
Adolescents 10-20 years

- N=148, 76% female
- Median base line CD4 184, Viral load 33,528, 4.53 $\log_{10}$
- 6 weeks VL= 49, 1.69 $\log_{10}$
- 12 weeks VL = 49, 1.69 $\log_{10}$
- 6 months VL = 49, 1.69 $\log_{10}$
- Deaths = 10
  - 6 before Rx, time = 23 days from screen
  - 4 on Rx, time = 54 days on treatment

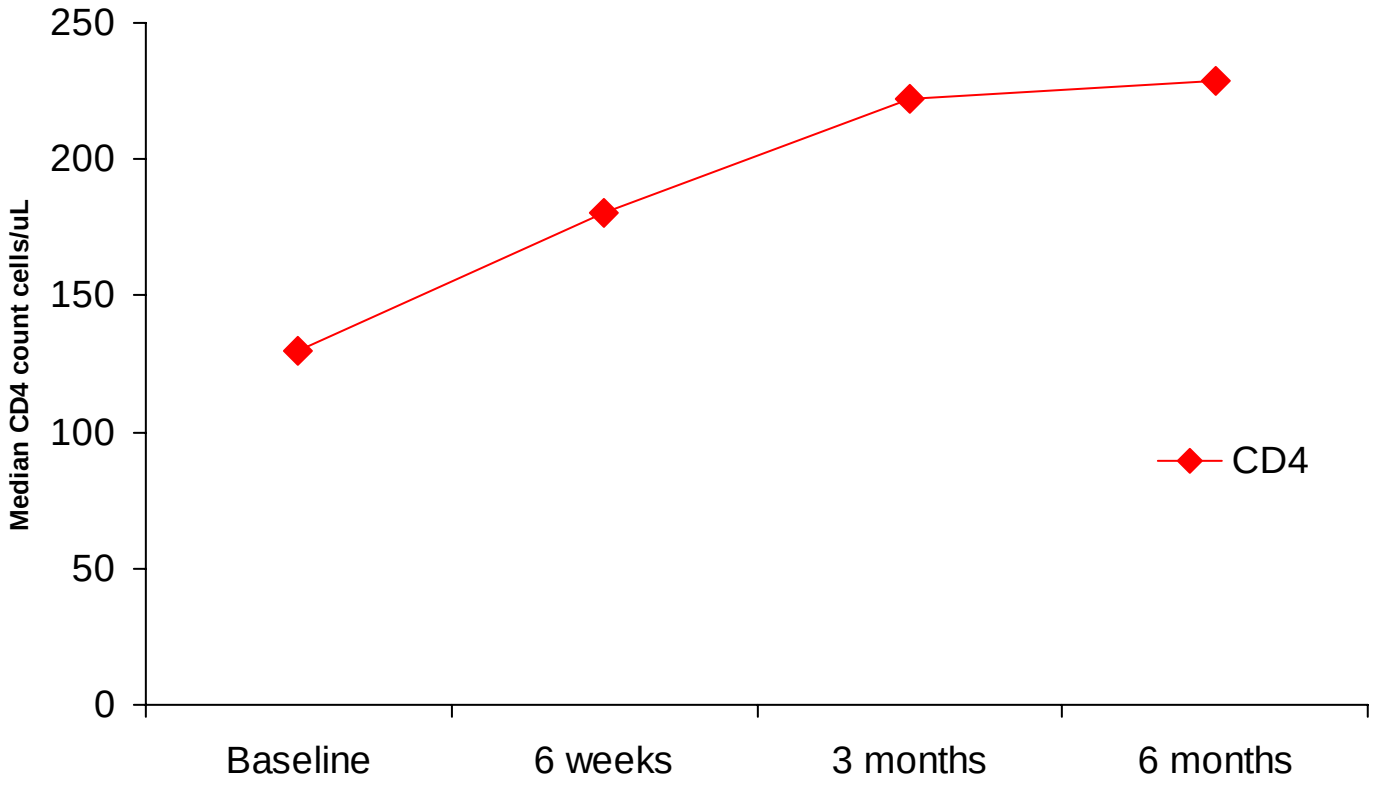
Adults >20 years

- N= 6657, 70.5% female, median age = 34 yrs
- Median base line CD4 130, Viral load 64,983, 4.81 $\log_{10}$
- 6 weeks VL= 49
- 12 weeks VL = 49
- 6 months VL = 49
- Deaths = 740
  - 438 before Rx, 60%
  - 302 on Rx, 40%

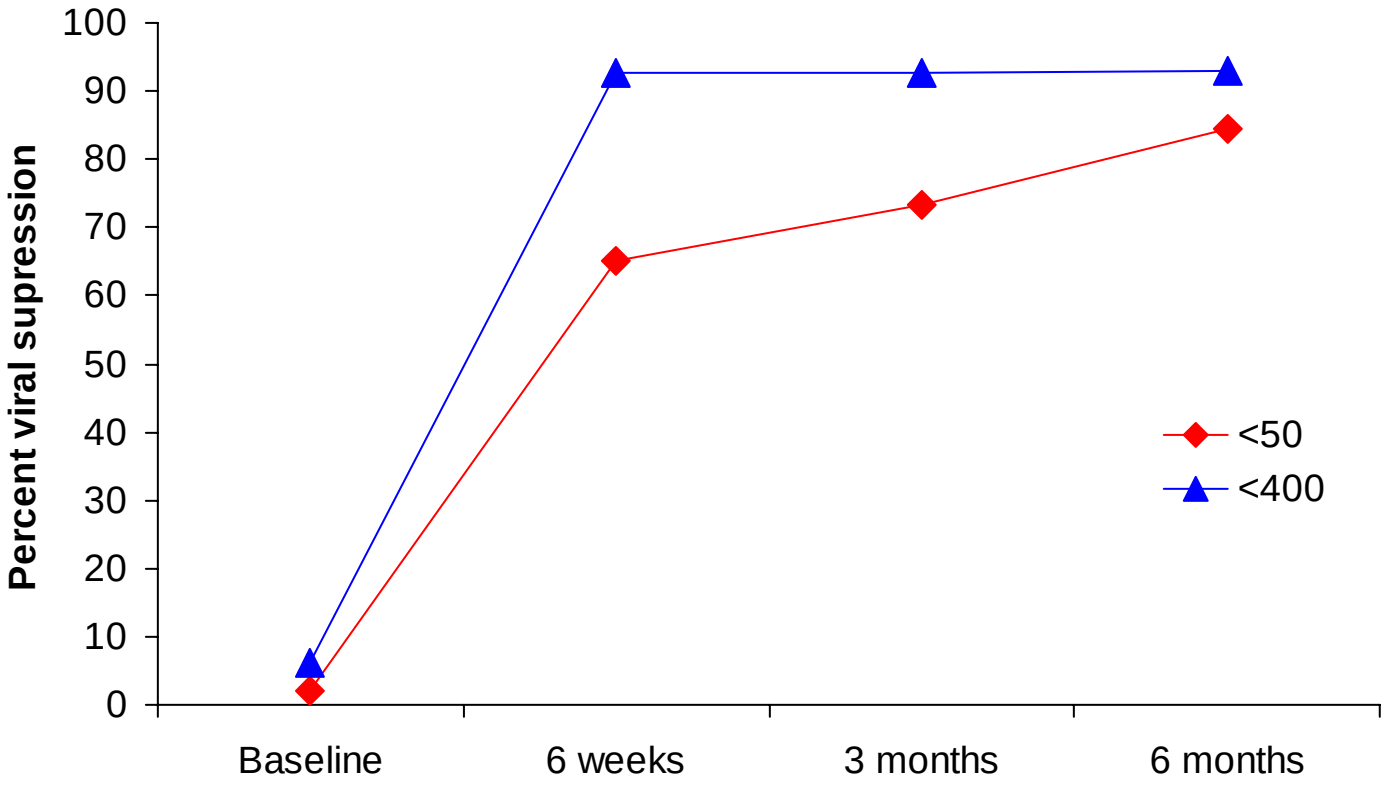
Programme Deaths before and after starting ART



Adult: CD4 response to ART



Adult: Viral response to ART



Initial Findings

- One of largest ART programmes worldwide
- Population is older than urban township programmes
- Patients are less advanced disease at entry
  - higher CD4
  - less AIDS
- Clinical staging data reliable
- Virological and CD4 outcomes are excellent
- Accessing children & women > men
- Mortality is high before starting HAART

Programme Evaluation Parameters*

- Time frame
  - Time of entry to programme
  - Time of loss to programme
  - Death/transfer/Los to follow up
- Drug data
  - Prescription collections
  - Drug switches, toxicity/tolerance/failure
- Laboratory data
  - Viral load, frequency?
  - CD4
  - Toxicity monitoring

*Not same as patient care parameters

A Quality Programme will Impact at Community Level

Must reduce morbidity

Must reduce mortality

Programme Evaluation

Must be more than just
numbers on programme